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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,125	11/21/2003	Franz Birke	01-1421	2235
28501 7590 09/17/2008 MICHAEL P. MORRIS BOEHRINGER INGELHEIM USA CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877-0368			EXAMINER HENLEY III, RAYMOND J	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 09/17/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/719,125

Applicant(s)

BIRKE ET AL.

Examiner

Raymond J. Henley III

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3 and 9-22 is/are pending in the application.
- 4a) Of the above claim(s) 9-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 13-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

CLAIMS 3 AND 9-22 ARE PRESENTED FOR EXAMINATION

On August 18, 2008, a request for continued examination, (RCE), under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicants' submission, including an amendment to claims 15, 16 and 18 and an addition of claims 20-22, filed on August 18, 2008 has been received and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restriction

As per the requirement for restriction set forth in the Office action dated February 16, 2006, claims 9-12 remain withdrawn from consideration on the merits under 37 C.F.R. § 1.142(b).

Claims 3 and 13-22 are herein acted on the merits.

Claim Rejection - 35 USC § 103

Claims 3 and 13-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderskewitz et al., (U.S. Patent No. 5,731,332, cited by Applicants) in view of Gregory et al., (U.S. Patent No. 6,172,096, cited by Applicants), each of record, for the reasons of record as set forth in the previous Office action dated May 16, 2008, as applied to claims 3 and 13-17, which reasons are here incorporated by reference, as well as those reasons set forth below which are in addition to the previous remarks by the Examiner.

Applicants' remarks at pages 6-7 of the RCE referenced at the outset of this Office action, as well as the claim amendment which adds claims directed to formulations containing specific ingredient proportions recite that the compound of formula 1A to meloxicam have been carefully considered, but fail to persuade the Examiner of error in maintaining this rejection.

Applicants have traversed the present rejection on the basis that the prior art fails to teach or suggest the allegedly synergistic results shown in the present specification and, in light of the Examiner's previous comments as well as the amendments to the claims, that the scope of the claims and of the data are commensurate.

In support of the above position, Applicants point to the specification Examples and offer that "[t]he applicants submit that the claimed proportions are fully supported by the example in the specification and the limitation 'wherein the composition has a weight ratio of formula (1A) to meloxicam of 1:20' [is also supported]", (Applicants' remarks at page 6, near the end of the second full paragraph).

As set forth in the previous Office action, the Examiner maintains that the data in the specification at page 16, lines 20-25, including the Examples pointed to by Applicants, establish a super-additive result which would not have been expected from the teachings of the prior art. Such super-additive results, however, would only be realized upon the practice of a method where the composition is administered. The step of administration of the composition is absolutely critical to realizing the unexpected results pointed to by the Applicants and recognized by the Examiner. Unfortunately, **none** of the claims are directed to a method of treatment commensurate in scope with the showing of unexpected results. A static formulation/composition simply cannot produce any of the results pointed to by Applicants

unless manipulated in such a manner where the active agents contact a body's receptors in a patient suffering from a given malady.

None of the claims relate to such a method and thus, the data in the specification cannot support a conclusion of non-obviousness.

Dosage Amounts/Ratios

Further, as previously noted, claim 3 contains a limitation that the compound of formula 1A to meloxicam is present at a ratio of 1:20. Also, claim 15 continues to recite a range of ratios of active agents while claim 16 recites a range of milligram amounts for the combination of actives. Unexpected results, however, have only been shown where the actives are employed in a method where a ratio of LTB4 antagonist:meloxicam of 1:20 and also when administered in a range of rates of administration which varied and were from 0.1 mg/kg formula IA / 2mg/kg meloxicam to 0.8 mg/kg formula IA / 16 mg/kg meloxicam. None of the present claims are directed to accurately reflect the ingredient ratio and amounts, much less a method of employing such ingredients.

Composition of Matter Not Unexpected

In order to maintain a clear record, the Examiner repeats from the previous Office action that the unexpected results relating to the treatment of inflammation demonstrated in the present specification are only realized when one practices a method of treating inflammation which includes a step of administering the active agents to a host. The present claims, however, are directed to compositions of matter and thus are not limited by an intended use or function or a step of administration, (see MPEP § 2111.02(II)). Thus, even if the present claims were limited

to the actual dosage amounts which provided the synergistic, anti-inflammatory results, the present claims would remain not commensurate in scope with such results.

Applicants Believe They Are Not Limited to the Exemplified Dosages

At pages 6-7, Applicants have presented their position that they are not limited to the exemplified dosages because "[t]he species here is [sic] more than sufficient written description for the claimed genus including that species....[t]he exemplified dosages are sufficient to show that the unexpected results at a weight ratio of 1:20 (formula (IA) to meloxicam) would be predictable over the claimed scope of dosages and would enable a skilled artisan to make and use the invention without under experimentation", (remarks bridging pages 6-7 of Applicants' remarks).

Applicants' remarks fail to persuade the Examiner of error because, in part, Applicants' remarks are directed to whether or not the claimed subject matter is enabled by the present specification. The present rejection, however, is not one under 35 U.S.C. § 112, first paragraph and thus Applicants' arguments directed to enablement are simply misplaced.

Further, while Applicants may wish the Examiner to accept that the showing in the specification is sufficient to support a finding that the claimed subject matter would not have been obvious, the Examiner cannot agree because (a) the claims are not directed to methods which is the subject of the data in the specification and (b) a broader range of results cannot be established from those shown because no scientific basis has been presented for the Examiner to believe that a showing of but one data point is supportive of the claimed ranges.

It is well established under 37 CFR 1.111(b) that a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims

patentably distinguishes them from the references is insufficient in overcoming a presumption of obviousness. Further well known is that arguments of counsel cannot take the place of factually supported objective evidence, (MPEP § 2145).

Accordingly, for the reasons above, the claims are properly rejected and none are in condition for allowance.

This is a continued examination of Application No. 10/719,125. All claims are drawn to the same/similar invention as previously claimed and could have been finally rejected on the grounds and art of record in the next Office action if they had been presented in response to a first action on the merits. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action following a Request for Continued Examination in this case. See MPEP § 706.07(b). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Raymond J Henley III/
Primary Examiner, Art Unit 1614

September 11, 2008